

**REMARKS**

Claims 1, 2, 5-9, 19, 23, 24, 26, 27, 29-33, 36-38, 40-43, and 65-77 are pending. By this response, claims 1 and 65 have been amended. No claims have been cancelled or added. As a result, claims 1, 2, 5-9, 19, 23, 24, 26, 27, 29-33, 36-38, 40-43, and 65-77 remain pending.

Without acceding to any of the grounds for rejection set forth in the Office Action, Applicants respond as follows:

**I. Double Patenting Rejections**

Claims 1-2, 5-7, 23, 26-27, 29, 31-32, 42-43, 65-69, and 74-76 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 11/036,029 to Saadat et al. In view of the provisional nature of the rejection, and without acceding to the contention of commonality of claimed subject matter between the two applications, Applicant will respond to this rejection at such time that it is asserted non-provisionally.

**II. Claim Rejections under 35 U.S.C. §102**

Claims 31-33, 36-38, 40-43, and 65-77 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Khalili (U.S. Patent Pub. No. 2005/0096502). For the reasons set forth below, Applicants respectfully traverse these rejections.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989).

**A. Claims 31-33, 36-38, 40-43**

Claim 31 recites a method for obtaining endoluminal access that includes the steps of:

advancing an elongate body having at least one articulatable element disposed near or at a distal region into a body lumen;

moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen provided in the elongate body; and

passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.

Specification support for these claim features was described in Applicant's prior response.

In its rejection of claim 31, the Office Action (at pp. 3-4) refers to the embodiment shown in FIGS. 13A-C of the Khalili publication and the accompanying description in the Khalili specification. However, the embodiment of the device shown in FIG. 13A-C of the Khalili publication does not include a "working lumen provided in the elongate body" and therefore its method of use does not include either of the step of "moving the articulatable element ... thereby at least substantially exposing a distal opening of a working lumen provided in the elongate body," or the step of "passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position." The Office Action identifies the camera 330 as allegedly corresponding with the recited "working lumen," but this is not a reasonable interpretation of term "working lumen" as used in claim 31. Not only does it fail to identify any structure in the Khalili device that corresponds with the recited "working lumen," but it also fails because the Khalili camera is a fixed component and is therefore not capable of being passed through any such working lumen.

Accordingly, because the Khalili publication fails to teach or describe at least the foregoing limitations recited in claim 31, there can be no anticipation of the claim – or of the claims dependent therefrom – by Khalili. Applicant requests withdrawal of the rejections of claims 31-33, 36-38, 40-43 and allowance of those claims.

**B. Claims 65-77**

Claim 65 recites an apparatus for obtaining endoluminal access that includes an elongate body, at least two working lumens, and at least one articulating element pivotally

connected to the elongate body by a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body. The claim has been amended to recite that the articulating element “articulates” from an in-line position to an off-axis position, and also recites that a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position. Specification support for these claim features was described in Applicant’s prior response.

In its rejection of claim 65, like claim 31, the Office Action (at pp. 3-4) refers to the embodiment shown in FIGS. 13A-C of the Khalili publication and the accompanying description in the Khalili specification. However, the embodiment of the device shown in FIG. 13A-C of the Khalili publication does not include “at least two working lumens extending through the elongate body,” nor does that embodiment include “at least one articulating element [that] articulates from an in-line position to an off-axis position” wherein a distal opening of at least one of the working lumens is substantially covered in the former and substantially uncovered in the latter. As noted above, the Office Action identifies the camera 330 as allegedly corresponding with one of the recited “working lumens,” but this is not a reasonable interpretation of term “working lumen” as used in claim 65. The Office Action fails to identify any structure in the Khalili device that corresponds with a “working lumen” that is substantially covered and uncovered by the at least one articulating element.

Accordingly, because the Khalili publication fails to teach or describe at least the foregoing limitations recited in claim 65, there can be no anticipation of the claim – or of the claims dependent therefrom – by Khalili. Applicant requests withdrawal of the rejections of claims 65-77 and allowance of those claims.

### **III. Claim Rejections under 35 U.S.C. §103**

Claims 1-2, 5-9, 19, 23-24, 26-27, and 29-30 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Khalili (U.S. Patent Pub. No. 2005/0096502) in view of Zehel (U.S. Patent No. 5,251,611). For the reasons set forth below, Applicants respectfully traverse these rejections.

To establish a *prima facie* case of obviousness under 35 U.S.C § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be

some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references(s) must teach or suggest all of the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Claim 1 recites an apparatus that includes an elongate body, at least two working lumens, and at least one articulating element pivotally connected to the elongate body by a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body. The claim has been amended to recite that the articulating element “articulates” from an in-line position to an off-axis position, and also recites that a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position. Specification support for these claim features was described in Applicant’s prior response.

As explained above in relation to claim 65, the embodiment of the device shown in FIG. 13A-C of the Khalili publication – which was also relied upon in the Office Action to reject claim 1 – does not include “at least two working lumens extending through the elongate body,” nor does that embodiment include “at least one articulating element [that] articulates from an in-line position to an off-axis position” wherein a distal opening of at least one of the working lumens is substantially covered in the former and substantially uncovered in the latter. As noted above, the Office Action identifies the camera 330 as allegedly corresponding with one of the recited “working lumens,” but this is not a reasonable interpretation of term “working lumen” as used in claim 1. The Office Action therefore fails to identify any structure in the Khalili device that corresponds with a “working lumen” that is substantially covered and uncovered by the at least one articulating element, as recited in claim 1.

The Zehel patent does not correct the deficiencies of the Khalili publication. Specifically, the Zehel patent does not teach or suggest a device in which “a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position.”

Accordingly, the combination of Khalili and Zehel fails to support a prima facie case of obviousness of claim 1. Claims 2, 5-9, 19, 23, 24, 26, 27, 29-30 each depend from claim 1, and each is patentable over the combination of Khalili and Zehel for the same reasons. Applicants request withdrawal of the rejections of all of the foregoing claims.

Accordingly, Applicants request withdrawal of the rejections of the pending claims, and issuance of a notice of allowance.

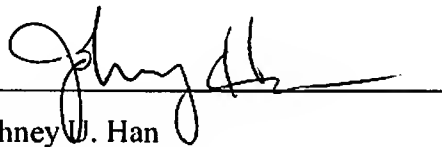
Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Similarly, unless explicitly stated, nothing contained or not contained in this paper should be construed as an assent to any of the Examiner’s stated grounds for rejecting the claims, including specifically the Examiner’s characterization of the teachings of the cited art and the Examiner’s contentions that any combinations of cited art would have been obvious. Rather, the present amendments to the claims and Remarks are an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ00700**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

  
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